



DT14 Rec'd PCT/PTO 12 OCT 2004

#41

Referenced  
in  
ROR

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wenbin Dang

Application No.: 10/500,795

Int'l Filing Date: January 9, 2003

For: Compositions for Treatment of  
Central Nervous System Neoplasms, and  
Methods of Making and Using the Same

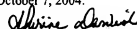
Examiner: Not yet assigned

Art Unit: Not yet assigned

Attorney Docket No.: GPT-030.01

CERTIFICATE OF MAILING

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Shirine M. Darvish

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR 1.97 (b)(3)**

Mail Stop Amendment  
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P.O. Box 1450  
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Sir:

In compliance with the requirements of 37 C.F.R. 1.56 and 1.97(b)(3), submitted herewith on Form PTO-1449 is a list of publications identified in a communication from the United States Patent and Trademark Office issued in a related application. Applicants respectfully request that the Examiner consider the listed publications and indicate they were considered by making appropriate notations on the attached Form 1449.

This submission does not represent that a search has been made or that no better art exists. Nor does it constitute an admission that the cited documents are material or constitute

"prior art." If the Examiner applies the listed documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents. Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the referenced documents be applied against the claims of the present application.

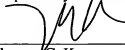
Applicants have listed dates of publication on the attached PTO-1449 for the cited documents based on information presently available to the undersigned. However, the listed publication dates should not be construed that the information in the cited documents was actually published or otherwise publicly available on the date indicated.

Under 37 C.F.R. § 1.97 (b)(3), this Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits; therefore, no fee is believed to be due in connection with this submission. However, the Commissioner is authorized to charge any deficiencies or credit any overpayment to/from our **Deposit Account, No. 06-1448, Reference GPT-030.01.**

Date: October 7, 2004

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Respectfully Submitted,



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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 3

## **Complete if Known**

Application Number	10/500,795
Filing Date	January 9, 2003
First Named Inventor	Dang
Art Unit	NYA
Examiner Name	NYA
Attorney Docket Number	GPT-030.01

## **U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No.†	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code* (if known)			
	AA	US-4,638,045	01-20-1987	Kohn, et al.	
	AB	US-5,219,564	06-15-1993	Zalipsky, et al.	
	AC	US-5,099,060	03-24-1992	Kohn, et al.	
	AD	US-6,040,330	03-21-2000	Hausheer, et al.	
	AE	US-8,017,935	01-25-2000	Mastalerz, et al.	
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	AJ	US-5,977,163	11-02-1999	Lie, et al.	
	AK	US-5,977,992	10-26-1999	Carver, et al.	
	AL	US-5,922,754	07-13-1999	Burchett, et al.	
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	AN	US-5,908,835	06-01-1999	Bissery	
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	AQ	US-5,877,205	03-02-1999	Andersson	
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	AT	US-5,821,363	10-13-1998	Wicnienski, et al.	
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	AV	US-5,808,888	09-15-1998	Susnjara, et al.	
	AW	US-5,795,909	08-18-1998	Shashoua, et al.	
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	BA	US-5,767,297	06-16-1998	Mandal, et al.	
	BB	US-5,767,298	06-16-1998	Terasawa, et al.	
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	BD	US-5,756,776	05-26-1998	Bombardelli, et al.	
	BE	US-5,750,691	05-12-1998	Nicolaou, et al.	
	BF	US-5,739,359	04-14-1998	Kingston, et al.	
	BG	US-5,728,687	03-17-1998	Bissery	
	BH	US-5,719,177	02-17-1998	Menichincheri, et al.	
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	BK	US-5,686,623	11-11-1997	Denis, et al.	
	BL	US-5,670,536	09-23-1997	Durr, et al.	
	BM	US-5,614,645	03-25-1997	Kingston, et al.	
	BN	US-5,608,087	03-04-1997	Nicolaou, et al.	
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	BQ	US-6,005,120	12-21-1999	Holton, et al.	
	BR	US-5,424,073	06-13-1995	Rahman, et al.	
	BS	US-5,547,981	08-20-1996	Greenwald, et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.D./



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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Sheet 2 of 3

## **Complete if Known**

Application Number 10/500,795  
Filing Date January 9, 2003  
First Named Inventor Dang  
Art Unit NYA  
Examiner Name NYA  
Attorney Docket Number GPT-003.01

## **FOREIGN PATENT DOCUMENTS**

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLA SS	Translation	
						YES	NO
	BT WO 00/57852	10/05/00	PCT				
	BU WO 00/41678	07/20/00	PCT				
	BV WO 98/44021	10/08/98	PCT				
	BW WO 98/44020	10/08/98	PCT				
	BX WO 98/48859	11/05/98	PCT				
	BY WO 02/30472	04/18/02	PCT				
	BZ WO 02/03957	01/17/02	PCT				
	CA WO 03/007914	01/30/03	PCT				
	CB WO 03/007915	01/30/03	PCT				

## **NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No.†	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CC	Gulman, et al., "Targeted Drug Delivery for Brain Cancer Treatment," Journal of Controlled Release, 65:31-41 (2000).	
	CD	Harper, et al., "Enhanced Efficacy of a Novel Controlled Release Paclitaxel Formulation (PACLIMER Delivery System) for Local-Regional Therapy of Lung Cancer Tumor Nodules in Mice," Clinical Cancer Research, 5:4242-4248 (1999), XP-000900829.	
	CE	Wen, et al., "New Biodegradable Polymer for Drug Delivery System Poly(D,L-Lactide-coEthyl Ethylene Phosphate)," Proceed. Intl. Symp. Control. Rel. Bioact. Mater. 27:664-665 (2000), XP-001094451.	
Not Published	CF	International Search Report for PCT/US03/00554.	
	CG	Beitz, et al., "Blood-Brain-Cerebrospinal Fluid Barriers," Basic Neurochemistry: Molecular, Cellular and Medical Aspects, Chapter 32, 5 <sup>th</sup> Edition, Edited by G.J. Siegel, et al., Raven Press, Ltd., New York, 1994.	
	CH	Brem, et al., "Placebo-Controlled Trial of Safety and Efficacy of Intraoperative Controlled Delivery by Biodegradable Polymers of Chemotherapy for Recurrent Gliomas," The Lancet, Volume 345, April 22, 1995, p. 1008-1012.	
	CI	Cahan, et al., "Cytotoxicity of Taxol In Vitro Against Human and Rat Malignant Brain Tumors," Cancer Chemother Pharmacol. (1994) 33:441-444, Springer-Verlag.	
	CJ	Chamberlain, et al., "Salvage Chemotherapy With Paclitaxel for Recurrent Oligodendrogliomas," Journal of Clinical Oncology, Vol. 15, No. 12 (December); pp. 3427-3432, American Society of Clinical Oncology.	
	CK	Chamberlain, et al., "Salvage Chemotherapy With Taxol for Recurrent Anaplastic Astrocytomas," Journal of Neuro-Oncology, 43: 71-8, 1999, Kluwer Academic Publishers, Netherlands.	
	CL	Choueka, Jack, et al., "Canine Bone Response to Tyrosine-Derived Polycarbonates and Poly (L-lactic acid)," Journal of Biomedical Materials Research, Vol. 31, 35-45 (1998), John Wiley & Sons, Inc.	



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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Sheet **3** of **3**

## **Complete if Known**

Application Number	10/500,795
Filing Date	January 9, 2003
First Named Inventor	Dang
Art Unit	NYA
Examiner Name	NYA
Attorney Docket Number	GPT-003.01

CM	Dordunoo, et al., "Taxol Encapsulation in Poly (ε-caprolactone) Microspheres," Cancer Chemother Pharmacol (1995) 36:279-282, Springer-Verlag.	
CN	Ertel, et al., "Evaluation of Poly (DTH carbonate), a Tyrosine-Derived Degradable Polymer, for Orthopedic Applications," Journal of Biomedical Materials Research, Vol. 29, 1337-1348 (1995), John Wiley & Sons, Inc.	
CO	Fountzilas, et al., "Radiation and Concomitant Weekly Administration of Paclitaxel in Patients with Glioblastoma Multiforme. A Phase II Study," Journal of Neuro-Oncology, 45:159-165, 1999, Kluwer Academic Publishers, Netherlands.	
CP	Glanz, et al., "Weekly, Outpatient Paclitaxel and Concurrent Cranial Irradiation in Adults With Brain Tumors: Preliminary Results and Promising Directions," Seminars in Oncology, Vol. 22, No. 5, Suppl. 12 (October), 1995: pp.28-32, W.B. Saunders Company.	
CQ	Glanz, et al., "Paclitaxel Disposition in Plasma and Central Nervous Systems of Humans and Rats with Brain Tumors," Journal of the National Cancer Institute, Vol. 87, No. 14, July 19, 1995.	
CR	Gupta, et al., "Cytotoxicity and Cell-Cycle Effects of Paclitaxel When Used as a Single Agent and in Combination with Ionizing Radiation," Int. J. Radiation Oncology Biol. Phys., Vol. 37, No. 4, pp. 885-895, 1997, Elsevier Science, Inc.	
CS	Hong, et al., "Taxol, Vincristine or Nocodazole Induces Lethality in G <sub>2</sub> Checkpoint-Defective Human Astrocytoma U373MG Cells by Triggering Hyperploid Progression," Carcinogenesis, Vol. 20, No. 7, pp. 1181-1188, 1999, Oxford University Press.	
CT	Langer, et al., Chemical and Physical Structure of Polymers as Carriers for Controlled Release of Bioactive Agents: A Review," Rev. Macromol. Chem. Phys., C23(1), 51-126 (1983), Marcel Dekker, Inc.	
CU	Leong, K. W., et al., "Polyanhydrides for Controlled Release of Bioactive Agents," Biomaterials, 1988, Vol. 7 September, Butterworth & Co. (Publishers) Ltd.	
CV	Prados, et al., "Phase II Study of Paclitaxel in Patients With Recurrent Malignant Glioma," Journal of Clinical Oncology, Vol. 14, No. 8 (August), 1996: pp. 2316-2321, American Society of Clinical Oncology.	
CW	Rosenthal, et al., "Phase II Study of Combination Taxol and Estramustine Phosphate in the Treatment of Recurrent Glioblastoma Multiforme," Journal of Neuro-Oncology, 47: 59-63, 2000, Kluwer Academic Publishers, Netherlands.	
CX	Sato, et al., "Pharmacokinetic Study of Taxol-Loaded Poly (lactic-co-glycolic acid) Microspheres Containing Isopropyl Myristate After Targeted Delivery to the Lung in Mice," Biol. Pharm. Bull. 19(12) 1596-1601 (1998), Vol. 19, No. 12, Pharmaceutical Society of Japan.	
CY	Suh, et al., "Regulation of Smooth Muscle Cell Proliferation Using Paclitaxel-Loaded Poly(ethylene oxide)-poly(lactide/glycolide) nanospheres," J. Biomed. Mater. Res, 42, 331-338, 1998, John Wiley & Sons, Inc.	
CZ	Walter, et al., "Intratumoral Chemotherapy," Neurosurgery, 37: 1129-1145, 1995.	
DA	Walter, et al., Interstitial Taxol Delivered From a Biodegradable Polymer Implant Against Experimental Malignant Glioma," Cancer Research 54, 2207-2212, April 15, 1994.	
DB	Wehbe, et al., "Histologic Evidence of a Radiosensitizing Effect of Taxol in Patients With Astrocytomas," Journal of Neuro-Oncology 39: 245-251, 1998, Kluwer Academic Publishers, Netherlands.	

Examiner Signature	/Paul Dickinson/	Date Considered	10/30/2008
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\*EXAMINER Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  
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